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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA AND STATE OF NEVADA *EX REL.* MICHAEL D. KHOURY, M.D., Plaintiffs, vs. INTERMOUNTAIN HEALTHCARE, INC. D/B/A INTERMOUNTAIN HEALTHCARE; IHC HEALTH SERVICES, INC.; MOUNTAIN WEST ANESTHESIA, L.L.C.; DAVID A. DEBENHAM, M.D.; ERIC A. EVAND, M.D; JOSHUA J. LARSON, M.D.; JOHN E. MINER, M.D.; TYLER W. NELSON, M.D.; AND DOE ANESTHESIOLOGISTS 1 THROUGH 150, Defendants.	**MOTION TO DISMISS FIRST AMENDED COMPLAINT AND MEMORANDUM IN SUPPORT** Civil No. 2:20-CV-00372 Judge Tena Campbell Magistrate Judge Cecilia M. Romero

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Pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), Intermountain Healthcare, Inc. d/b/a Intermountain Healthcare and IHC Health Services, Inc. ("Intermountain")[1] moves to dismiss Michael D. Khoury, M.D.'s ("Relator") First Amended Complaint ("FAC").

I. STATEMENT OF RELIEF SOUGHT AND GROUNDS FOR MOTION

In his False Claims Act ("FCA") lawsuit, Relator assails how professional services were provided by Mountain West Anesthesia, LLC ("MWA")—an independent physician group—and MWA's employed anesthesiologists. Relator alleges that because MWA's anesthesiologists used personal electronic devices ("PEDs'") during surgery, MWA violated the FCA when it submitted claims to federal health care programs for professional services rendered by those allegedly distracted physicians. Though framed in sensationalist terms as an exercise in altruism, what Relator really seeks to do is commandeer the FCA—a fraud statute—to police the conduct of physicians in the operating room. Unfortunately for Relator, the Tenth Circuit has rejected this very premise because the FCA and its punitive remedial scheme is not an appropriate vehicle for monitoring technical compliance with complex regulations.

Even beyond this existential flaw in Relator's action, there are two additional shortcomings that are fatal to the FAC. First, though Intermountain has no role in preparing or submitting MWA's claims and did not itself submit any claims for professional anesthesiology services—and therefore made no representations regarding how the physicians administered anesthesia—Relator

[1] Relator refers to Intermountain Healthcare, Inc. and IHC Health Services, Inc. both as "Intermountain." Relator ignores the distinction between these two entities, as he does for the distinctions between all defendants throughout the FAC. Intermountain Healthcare, Inc. does not operate hospitals or submit any claims for reimbursement. It is the parent of IHC Health Services, Inc., which operates the hospital at issue. Because there are no specific allegations against Intermountain Healthcare, Inc., that entity should be dismissed from this lawsuit. For purposes of this motion, Intermountain and IHC are collectively referred to as Intermountain.

seeks to hold Intermountain liable based solely on those services being performed in one of its hospitals and Intermountain billing for the supplies and facilities used during the surgeries. Relator's attempt to tether Intermountain's technical services claims to the separate professional services claims of the physicians is untenable as a matter of law.

MWA is an anesthesiology group completely independent of Intermountain who submitted claims solely for the professional services rendered by its physicians. Intermountain submitted its own separate claims for the supplies and facilities it provided during surgeries. Though MWA and Intermountain's claims are submitted for different items and services on distinct claim forms, are reimbursed by different components of the Medicare program, and are subject to separate requirements governing the submission and reimbursement of claims, Relator still inexplicably attempts to impute the alleged improper provision of professional services to Intermountain without focusing on the substance of what actually was included on the claims submitted by Intermountain. The gaping holes in Realtor's imputed liability theory are magnified by what he fails to allege about Intermountain's conduct. Nowhere in the FAC does Relator allege that Intermountain failed to provide any of the items or services on its hospital claims, or those items and services were provided in a substandard or deficit way. Instead, the FAC actually alleges that the Government received the benefit of its bargain and exactly the items and services it expected and for which it paid Intermountain.

Second, even if Relator could somehow impute MWA's conduct or alleged submission of false claims to Intermountain, Relator still fails to satisfy the condition precedent, pleading violations of the Medicare regulations and requirements for anesthesia professional services. While Relator eschews the actual standards applied by Medicare—instead opting to invent his own—Relator's fabricated requirements for anesthesia services do not override those promulgated

by the Government. As a result, Relator fails to plead that MWA (much less Intermountain) violated a material law, regulation, or requirement, triggering FCA liability.

Against this backdrop, it is unsurprising that the United States, after investigating and reviewing the FAC, declined to intervene in this matter. Given the glaring issue with Relator's allegations and theories of liability, the FAC should be dismissed under both Rules 12(b)(6) and 9(b), as outlined below.

II. LEGAL STANDARDS

A. Rule 12(b)(6) and 9(b) Standards

On a Rule 12(b)(6) motion to dismiss, the factual allegations within a complaint "must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). At this stage of the proceedings, a court must accept all the well-pleaded allegations of the complaint as true and must construe them in the light most favorable to the plaintiff. *Moffett v. Halliburton Energy Servs., Inc.*, 291 F.3d 1227, 1231 (10th Cir. 2002). However, a court need not accept as true those allegations that are conclusory in nature. *Erikson v. Pawnee Cnty. Bd. Cnty. Comm'rs*, 263 F.3d 1151, 1154–55 (10th Cir. 2001); *Hall v. Bellmon*, 935 F.2d 1106, 1109–10 (10th Cir. 1991) ("[C]onclusory allegations without supporting factual averments are insufficient to state a claim upon which relief can be based.").

Rule 9(b)'s heightened pleading requirements apply to FCA claims. *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 745 (10th Cir. 2018). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A plaintiff must, at a minimum, set forth the "who, what, when, where, and how of the alleged fraud" to comply with Rule 9(b). *Polukoff*, 895 F.3d at 745.

B. Statutory Background: The False Claims Act

The FCA imposes liability on any person who "knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). To plead cognizable false claims or false records causes of action, a plaintiff must allege: "(1) a false statement, [false record,] or fraudulent course of conduct; (2) made with the requisite scienter; (3) *that is material*; and (4) that results in a claim to the Government." *United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 539 (10th Cir. 2020) (applying these four factors to false claims, false records, and reverse false claims under the FCA).

"[F]alse or fraudulent" includes both *factually* false and *legally* false requests for payment. *United States ex rel. Lemmon v. Envirocare Utah, Inc.*, 614 F.3d 1163, 1167–68 (10th Cir. 2010). Complaints asserting factually false claims must generally plead that the defendant "submitted 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'" *Id.* at 1168 (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). A complaint asserting a legally false claim must plead that there was a "knowingly false certification of compliance with a regulation or contractual provision as a condition of payment." *Lemmon*, 614 F.3d at 1168.

For legal falsity, plaintiffs may assert claims based on both implied and express false certification theories. *Id.* Claims under an express false certification theory arise when a defendant "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Conner*, 543 F.3d at 1217 (quoting *Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001), *abrogated on other grounds by Universal Health Servs., Inc. v.*

United States ex rel. Escobar, 136 S. Ct. 1989 (2016) [hereinafter *Escobar*]). Claims under an implied false certification theory arise where "through the act of submitting a claim, a [defendant] knowingly and falsely implied that it was entitled to payment." *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1169 (10th Cir. 2016). The implied certification theory can be a basis for liability where: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 136 S. Ct. at 2001.

Not every alleged falsehood is actionable under the FCA. *Id.* at 2003 (recognizing that the FCA is not an "all-purpose antifraud statute"). For claims based on either theory—of implied or express false certification—only acts that are "material" to the government's payment decision prompt liability. *Id.* at 2002–03. In other words, the misrepresentation alleged, whether express or implied, is actionable under the FCA "only if it leads the government to make a payment which it would not otherwise have made." *Conner*, 543 F.3d at 1219. In *Janssen*, the court identified three non-exclusive factors that courts may consider in evaluating materiality in a FCA case: (1) whether the Government consistently refuses to pay similar claims, or continues to pay claims, despite knowledge of noncompliance; (2) whether the noncompliance goes to the "very essence of the bargain" or is only "minor or insubstantial;" and (3) whether the Government has expressly identified a provision as a condition of payment. *Escobar*, 136 S. Ct. at 2003 & n.5.

III. ARGUMENT

A. Relator Fails to Allege Intermountain's Claims Were Factually False

Relator asserts a deeply flawed theory of factual falsity and asks this Court to: (1) apply a fictitious standard for the reimbursement of anesthesia services; (2) incorrectly tether

Intermountain's distinct claims for hospital-based anesthesia services ("Technical Services") to those submitted by MWA for physician-based anesthesia services ("Professional Services"); and, (3) overlook glaring materiality issues concerning the reimbursement of anesthesia services. The Court should reject Relator's invitation and dismiss the FAC with prejudice under Rule 12(b)(6) because Intermountain's claims were not factually false.

1. Relator invents a fictitious standard for the reimbursement of Professional Services to support his factual falsity argument.

The FAC alleges that MWA's Professional Services claims were factually false because it reported "anesthesia time" covering entire surgical procedures without accounting for time MWA physicians were allegedly distracted by their PEDs or for other reasons. FAC ¶¶ 10, 188–89. The Complaint also asserts that MWA submitted false claims using a CPT code modifier indicating that the services were "personally performed." *Id*. Relator then makes the unsupported leap that because MWA's Professional Services claims allegedly were factually false in misreporting the "anesthesia time" and MWA physician's role in performing the services, Intermountain's separate claims for Technical Services were false as well. *Id*. ¶¶ 191, 260. [2]

Not only is Relator's theory of individual liability against Intermountain fatally flawed, Relator's entire theory is premised on a fictional standard for billing anesthesia Professional

[2] Intermountain further adopts and incorporates by reference the arguments made by MWA and the individual physician defendants in support of their respective motions to dismiss.

Services that is directly contradicted by the Medicare regulations,[3] manual provisions and guidance addressing how "anesthesia time" is calculated, and what it means for anesthesia services to be "personally performed." Because the FAC fails to allege (as a matter of law) that MWA incorrectly reported "anesthesia time" or that MWA improperly used the "personally performed" CPT code modifier for Professional Services, MWA's claims cannot be factually false and, because Relator's claims against Intermountain are entirely derivative on how MWA billed for Professional Services, Intermountain's claims likewise cannot be factually false.

a) Physical presence is the correct standard for calculating "anesthesia time."

The overarching—but incorrect—theme in Relator's FAC is that "anesthesia time" reported on MWA's claims should have accounted for—and subtracted—time when anesthesiologists were physically present in the operating room and anesthesia was being administered to patients, but the physicians were allegedly distracted by their PEDs. *Id.* ¶¶ 9–10 ("[I]n this case, the Defendant Anesthesiologists reported that entire surgeries . . . were 'anesthesia time,' even when they spent the vast majority of the surgery ignoring the sedated patient to focus on their PEDs."). However, the Medicare regulation and related guidance did not obligate MWA to deduct time when its anesthesiologists were physically present in the operating room and anesthesia services were occurring, even if the physicians were allegedly distracted by a PED, the radio, a newspaper, or simply daydreaming.

[3] The Complaint focuses entirely on Medicare standards without explaining the standards for other federal healthcare programs including Medicaid, TRICARE, or Medicare Advantage. *See, e.g.*, FAC ¶¶ 112–22. Relator's claims concerning those payers included in Counts One through Four, fail as a matter of law and should be dismissed under Rule 12(b)(6) and Rule 9(b). Similarly, Relator's failure to plead the underlying requirements for claims submission and reimbursement under Nevada Medicaid warrants dismissal of Count Five, alleging violations of the Nevada False Claims Act.

As a starting point, Medicare defines "anesthesia time" as:

> [T]he time during which an anesthesia practitioner *is present with the patient*. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner *is no longer furnishing anesthesia services to the beneficiary*, that is, *when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service.* In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

42 C.F.R. § 414.46(a)(3) (emphasis added).

Section 414.46 starts the clock for "anesthesia time" when the anesthesiologist is physically present with the patient to initiate anesthesia services ("starts when the anesthesia practitioner begins to prepare the patient") and stops the clock only when anesthesia ends and the patient can be transitioned from the operating room to postoperative care ("ends when the anesthesia practitioner is no longer furnishing anesthesia services . . . when the beneficiary may be placed safely under postoperative care."). *Id*. It is also noteworthy that Medicare describes "anesthesia time" as a "*continuous* time period" that runs from the start of anesthesia until its end. *Id.* (emphasis added). Nowhere in this standard is there any requirement to remove periods of time when an anesthesiologist is still present with the patient and anesthesia services are ongoing, but the anesthesiologist is potentially distracted. *See id.*

In contrast, Relator's fictitious standard asserts that this regulation requires "continuous[] monitoring" unbroken by any distraction, and deductions for time during which the anesthesiologist is physically present but potentially distracted. *See, e.g.*, FAC ¶¶ 2, 15, 188–90, Ex. 2 at 6–7. Relator is incorrectly grafting the phrase "monitoring services" from the definition of "base unit" in Section 414.46(a) and reading it into the definition of "anesthesia time" to show that those "monitoring services" govern MWA's reporting of "anesthesia time." FAC ¶ 108. But

Section 414.46(a)(1) states that the "base unit" "reflects all activities *other than anesthesia time*," including "preoperative and postoperative visits, the administration of fluids and blood incident to anesthesia care, *and monitoring services*." 42 C.F.R. § 414.46(a)(1) (emphasis added). The "base unit" which includes "monitoring services," is distinct from and does not include "anesthesia time," nor does it require that "monitoring services" be used to calculate "anesthesia time." Relator's factual falsity argument is thus based on an incorrect reading of the regulatory text.

The Final Rule promulgated by the Centers for Medicare & Medicaid Services ("CMS") implementing revisions to the Medicare Physician Fee Schedule for Calendar Year 2000 offers additional clarity about how "anesthesia time" is calculated and that physical presence is the barometer for "anesthesia time" used by CMS:

> Anesthesia time, as defined under § 414.46(a)(2), starts when the anesthesiologist or CRNA [certified registered nurse anesthetist] prepares the patient for anesthesia care and ends when the anesthesiologist or CRNA *is no longer in personal attendance*; that is, when the patient is placed under postoperative care. While in most instances the anesthesiologist or CRNA *remains continuously with the patient from the establishment of venous access to the conclusion of anesthesia attendance*, there may be instances when there are breaks in the *continuous presence of the anesthesiologist* or CRNA.

64 Fed. Reg. 59380, 59409 (Nov. 2, 1999) (emphasis added).

Even the guidance cited by Relator from Noridian—the Medicare administrative contractor to whom MWA submitted claims—establishes that "anesthesia time" is tied to the physical presence of an anesthesiologist during a surgical procedure, not their continuous attention. FAC ¶ 117. Specifically, Noridian explained that medical records covering anesthesia services should include an "[i]ntra-operative report with anesthesia time (beginning of services, *any time spent away from beneficiary* and discontinuance of services)." Noridian Healthcare Sols., Anesthesia

and Pain Management (Apr. 15, 2021) [hereinafter "Noridian Guidance"] (emphasis added).[4] Though Relator tries to sidestep the obvious import of the Noridian Guidance, "time spent away" refers to time when the anesthesiologist is out of the room, not time spent on an iPad. *Id.*

Despite the sources described above tying "anesthesia time" to physical presence and ongoing anesthesia services, Relator clings to the idea that distractions like PEDs constitute an interruption in anesthesia time or discontinuance of services that must be deducted from MWA's claims. *See, e.g.*, FAC ¶¶ 115–18 (referencing regulatory definitions of "interruptions," Noridian Guidance, and the Medicare Claims Processing Manual ("Medicare Manual")). Yet again, Relator concocts a standard with no basis in Medicare's requirements. While under the relevant regulations physicians must report a "discontinuance of services" or "interruption[s] of anesthesia time," § 414.46(a)(3), CMS and Noridian consider an "interruption" or "discontinuance" to be a situation where the anesthesia services are literally halted because for example, a patient is moved from one location to another, or surgical services (and anesthesia) must be stopped because water is leaking onto the operating room floor. *See* 64 Fed. Reg. 39608, 39624 (July 22, 1999) (examples of situations where a "discontinuance" of anesthesia time occurs); Noridian Guidance (defining "discontinued anesthesia"). None of the scenarios contemplated by CMS or Noridian cover Relator's legally flawed theory that "distraction by PED" constitutes an interruption or discontinuance of "anesthesia time" warranting a deduction to MWA's claims.

To evade the aforementioned contrary authorities, Relator leans on numerous American Society of Anesthesiologists (the "ASA") publications, introduces a "vigilance" requirement not found in the Medicare regulations or related guidance, and even relies on the Merriam-Webster

[4] Available at https://med.noridianmedicare.com/web/jeb/specialties/anesthesia-pain-management.

definition of "continuous." FAC ¶¶ 87–99, 116. But these sources cannot trump Medicare's own regulatory payment policy for anesthesia services. Further, the ASA itself actually issued guidance confirming that physical presence is essential factor for determining "anesthesia time" and "discontinuous periods" of anesthesia services. *See 2019 Relative Value Guide Updates Include Anesthesia Time and Field Avoidance*, American Society of Anesthesiologists[5] ("Discontinuous periods occur when there is an interruption in anesthesia services and the anesthesiologist is temporarily *not in attendance* for direct monitoring and care of the patient, despite not having completed the surgical procedure . . . It is important to note that discontinuous time is NOT to be used while the surgical procedure is underway.").[6]

Finally, Relator offers a self-serving and ill-conceived declaration from Rebecca Busch (the "Busch Declaration"), which includes Ms. Busch's opinions and legal conclusions despite her having no actual, firsthand knowledge about the facts in this case or the allegations in the FAC. *See* FAC Ex. 2. Through the Busch Declaration, Relator outsources his obligations to marshal and argue the law supporting his claims and attempts to usurp the Court's role in interpreting the Medicare regulations by offering Ms. Busch's "expert" view of those sources. *Id*. at 5. The Court should disregard the Busch Declaration for precisely these reasons, and because it is clear Ms. Busch bases her opinions not on the actual Medicare payment standards, but instead on non-binding ASA publications and her own views of the Defendants' alleged conduct, as reported to

[5]Available at: https://www.asahq.org/quality-and-practice-management/managing-your-practice/timely-topics-in-payment-and-practice-management/2019-relative-value-guide-updates-include-anesthesia-time-and-field-avoidance (last visited Aug. 26, 2021).

[6] When ruling on a motion to dismiss pursuant to Rule 12(b)(6) courts may consider materials in addition to the complaint, such as "matters of which a court may take judicial notice." *Gee v. Pacheco*, 627 F.3d 1178, 1186 (10th Cir. 2010)).

her by Relator. And when Ms. Busch asserts that mere physical presence "does not satisfy the conditions of payment for personally performed anesthesia services" she does so by creating a "continuous[] monitoring" requirement wholly absent from the applicable regulation about "anesthesia time." *Compare* Dkt. 52-2 at 6–7, *with* C.F.R. § 414.46(a)(3), (c).

Because the calculation of "anesthesia time" is tied to the physical presence of the anesthesiologist and not some nebulous standard based on distraction—which would be impossible to apply—MWA's reporting of "anesthesia time" on its claims was correct and Relator fails to allege factual falsity.

b) Modifier AA—which indicates "personally performed" anesthesia services—does not make representations about the level of monitoring that was performed.

Rather than discerning the meaning of and representations made by Modifier AA—for "personally performed" anesthesia services—from Section 414.46 or the Medicare Manual guidance, Relator instead opts to apply his own definition. FAC ¶¶ 15, 189–90 (discussing Modifier AA). Contrary to the FAC's allegations, Modifier AA provides CMS with information about an anesthesiologist's supervision or direction of personnel and is not used to describe the level of attention or monitoring provided by the anesthesiologist. Accordingly, Relator's factual falsity arguments based on Modifier AA are unsuccessful.

Under Section 414.46, there are three ways an anesthesiologist may render anesthesiology services: "personally performed," "medically directed," or "medically supervised." C.F.R. § 414.46(c), (d), (f). "Personally performed" services are those where the physician performs the

entire service alone. *Id*. § 414.46(c)(1)(i).[7] "Medically directed" or "medically supervised" services are those where the physician is *directing or supervising* qualified personnel in multiple concurrent procedures. *Id*. § 414.46(d), (f). Stated differently, when an anesthesiologist is working alone or does not direct or supervise trainees (like residents and fellows) or CRNAs in more than one concurrent procedure, those services are "personally performed," and when supervising lower-level personnel in multiple procedures at the same time, those services are "medical directed" or "medically supervised." Given the distinctions Section 414.46 draws between the way anesthesiology services can be provided, it should be obvious that when an MWA physicians *was the only clinician rendering anesthesia services to a patient*, those services were "personally performed." *See* FAC ¶ 88.

Relator, however, argues that Modifier AA somehow made representations not only about whether the anesthesiologist was working alone in the operating room, but also about the level of attention or monitoring that the MWA physician provided during the procedure. FAC ¶ 190. Relator's position is illogical and legally untenable. The narrow purpose of the anesthesia claims modifiers is to alert CMS about whether the physician was providing the services or was directing and supervising others, possibly in multiple concurrent procedures. Based on the personnel being supervised and number of procedures occurring concurrently, CMS can then use the modifiers to determine the level of reimbursement. But nowhere in Section 414.46(c) or the Medicare Manual is there any indication that the modifier being appended to a claim for anesthesia services reflects

[7] In situations where a teaching physician supervises or is training residents, CRNA students or CRNAs in a single procedure, those services are also considered "personally performed." *Id*. § 414.46(c)(1)(iii)–(vi).

for example, during what percentage of the surgery was the anesthesiologist staring at the patient's vital signs or was "actively and personally monitoring" the patient. FAC ¶ 190.

Relator is asking the Court to read into Section 414.46 requirements that simply do not exist. *See, e.g.*, FAC Ex. 2 at 6–7. Because MWA's use of Modifier AA accurately represented that one of its physicians provided the anesthesia services alone and was not supervising or medically directing other personnel, Relator's factual falsity argument in this regard also fails.

2. Even if MWA's claims were factually false, Intermountain's separate claims for distinct items and services were not.

Relator overlooks the indisputable fact that Intermountain's claims for Technical Services are separate from those covered by MWA's Professional Service claims. Even if this Court were to find that Relator has successfully alleged that MWA's claims were factually false, the veracity of Intermountain's claims must be evaluated on their own. And, notwithstanding Relator's attempt to blend the two, the rules governing Medicare Part A reimbursement for Technical Services are completely different than those governing Medicare Part B reimbursement of physician Professional Services. As a result, Relator's factual falsity allegations are deficient as a matter of fact and law, warranting dismissal under Rule 12(b)(6) and Rule 9(b).

As Relator acknowledges, "hospitals and surgery centers are reimbursed for their facility costs associated with delivery of anesthesia care, such as use of the operating room, anesthesia drugs, and the supplies and equipment for administering and monitoring anesthesia. FAC ¶ 140 (citing 42 C.F.R. §§ 409.10, 419.2(b), 416.120(c)). Significantly too, Medicare coverage and payment for hospital services whether inpatient or outpatient, *specifically exclude physician services* from their scope. *See* 42 C.F.R. § 415.102(a) (inpatient services); 42 C.F.R. § 419.22(a)

(outpatient services). Hospitals submit claims for their Technical Services, including anesthesia drugs and supplies on CMS Form 1450 claims. FAC ¶ 141 (citing 42 C.F.R. § 424.32).

Meanwhile, physicians receive reimbursement for their anesthesia professional services based on the corresponding CPT codes and modifiers which report the duration of the Professional Services (i.e., "anesthesia time"), and the anesthesiologist's level of involvement in providing those Professional Services (supervisory or direct). Claims for anesthesia Professional Services are submitted on a different form than those for Technical Services, a CMS Form 1500 claim. FAC ¶¶ 111, 124 (citing 42 C.F.R. § 424.32(b)).

Because Intermountain's claims only sought payment for its distinct Technical Services and not the MWA physicians' Professional Services, MWA's claims have *no* bearing on whether Intermountain's claims were factually false. Relator does not allege that Intermountain failed to provide the operating room, anesthesia drugs, or the supplies and equipment for administering and monitoring anesthesia which were included on its claims. Even if Relator had successfully alleged that MWA reported inflated amounts of "anesthesia time" because it included periods when MWA physicians were distracted by PEDs, Intermountain was still entitled to bill for the Technical Services for use of the operating room, anesthesia drugs, and the supplies and equipment. As Relator alleges, all the patients who received anesthesia at Dixie Regional Medical Center *were in its operating room, receiving its anesthesia drugs, and were monitored by Intermountain's nursing staff*. *See, e.g.*, *United States ex rel. Williams*, No. 3:12-CV-0371-B, 2014 WL 3353247, at *5 (N.D. Tex. July 9, 2014) (dismissing claims based on allegedly false claims where "the government is alleged to have received exactly what it paid for"). In other words, the Technical Services on Intermountain's claim forms were all provided and what Relator claims was false (time

under anesthesia) could only appear on a claim for Professional Services and not Technical Services.

To be clear, Relator's allegations about Intermountain's are demonstrably false. The FAC asserts that Intermountain reported the anesthesia time units—as recorded by the MWA physicians—and included Modifier AA with the anesthesia procedure code on its Technical Services claims. FAC ¶ 150. These allegations are a complete fabrication. Relator provides no citations to the regulations, Medicare Manuals, or any other guidance in support of this allegation. Instead, he co-opts the billing rules for MWA's Professional Service claims and indiscriminately applies them to Intermountain. But the requirements for Professional Services do not apply to Technical Services given that each seeks payment for distinct items and services and are paid for by separate components of the Medicare program. *See* FAC ¶¶ 52–53 (distinguishing Medicare Part A and Part B). It should have been apparent to Relator that every requirement he cites in the FAC concerning billing for anesthesia services *relates solely to MWA's Professional Services and not Intermountain's Technical Services*. *Id*. ¶¶ 108–22.[8]

At the same time, the Medicare Manuals for inpatient and outpatient hospital services say nothing about recording anesthesia time based on the units recorded by the physician, or the use of Modifier AA—and these are not included on Intermountain's claim forms. *See generally* CMS, *Medicare Claims Processing Manual, Chapter 3—Inpatient Hospital Billing*, Pub. 100-04 (Mar.

[8] Every source Relator invokes pertains exclusively to physician services. *See* 42 U.S.C. § 1395w-4; 42 C.F.R. §§ 414.46, 414.60, 415.11; Centers for Medicare and Medicaid Servs., Dep't Health & Human Servs. ("CMS"), *Medicare Claims Processing Manual, Chapter 12—Physicians/Nonphysician Practitioners*, Pub. 100-04, § 50.G (May 3, 2021), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf; CMS, *Medicare Claims Processing Manual, Chapter 26—Completing and Processing Form CMS-1500 Data Set*, Pub. 100-04, § 10.9 (Sept. 4, 2020) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26crosswalk.pdf; The Noridian Guidance.

31, 2021);[9] CMS, *Medicare Claims Processing Manual, Chapter 4—Part B Hospital*, Pub. 100-04 (July 14, 2021).[10] Guidance issued by Noridian concerning the use of surgical and procedure modifiers by hospitals only reinforces Intermountain's position, as Modifier AA is exclusively mentioned for use by critical access hospitals that have elected a billing method *which includes physician professional services* on its hospital claims. *See* Noridian Healthcare Sols., Modifiers (Aug. 13, 2021) (billing instructions related to critical access hospitals).[11]

Curiously, while Relator provides legal authority when describing Intermountain's Medicare enrollment form, how it is reimbursed for surgical care, and the form it uses to submit claims, when it comes time to describe the *actual information included on its claims*, all the FAC offers is an unadorned legal conclusion that Intermountain reported anesthesia time and used Modifier AA. *Compare* FAC ¶¶ 131, 140–43, 146–49, *with* FAC ¶ 150. The Court should disregard Relator's conclusory allegations about the information reported on Intermountain's claims that lack the well-pled facts required by Rule 12(b)(6). *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009) (finding "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions").

Additionally, Rule 9(b) requires dismissal because to demonstrate a FCA violation, Relator must "show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Lemmon*, 614 F.3d at 1167.

[9] Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.

[10] Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.

[11] Available at: https://med.noridianmedicare.com/web/jfa/topics/modifiers#critical-access-hospital.

Here, Relator cannot even clearly articulate how Intermountain billed for its Technical Services, including what information it placed on claims, or what rules governed the completion of those claims. Absent this critical information, Relator has no chance of creating a "reasonable inference" that Intermountain submitted false claims, and Rule 9(b) requires dismissal of his action.

3. Anesthesia services included on Intermountain's claims did not affect Medicare reimbursement amounts and were therefore not "material."

To bring a cause of action under the FCA, Relator must establish that any alleged falsehoods were "material" to the government's payment decisions. *Escobar*, 136 S. Ct. at 2004. Even if Relator could demonstrate that Intermountain submitted factually false claims (which he cannot) any anesthesia services included on those claims did not impact Medicare reimbursement. Any alleged misrepresentations were therefore not material. *Janssen*, 949 F.3d at 539.

Relator appears to concede this point by acknowledging that Medicare paid Intermountain for its Technical Services on a lump sum basis. FAC ¶ 145. The FAC is correct that Medicare used a Diagnosis Related Group ("DRG") to reimburse Intermountain for inpatient care, and an Ambulatory Payment Classification ("APC") for outpatient care. *Id*. ¶¶ 146, 148. Under both the DRG and APC methodologies, hospitals are paid a predetermined amount, irrespective of the actual items and services that are rendered. *See* 42 C.F.R. § 412.2(a), (b)(1) (DRG payments); 42 C.F.R. § 419.2(b) (APC payments). Said differently, even if Intermountain overreported anesthesia time because MWA physicians were allegedly distracted by their PEDs, that would not impact Intermountain's reimbursement and any claims Intermountain submitted would not be actionable under FCA. *Janssen*, 949 F.3d at 539 (holding that the FCA "does not impose liability for any and all falsehoods" and instead only reaches conduct "where the alleged misrepresentations are material to the government's payment decision").

Sensing defeat on this point, Relator pivots and alleges that CMS revises the payment rates each year to reflect the cost of certain services—including anesthesia—based on data from hospitals' claims, and therefore, the anesthesia component reported by Intermountain is material to future payment amounts. FAC ¶¶ 147, 149. To say Relator's theory is a stretch is a massive understatement.

First, Relator's perfunctory allegations about the potential inflation of future DRG and APC payment rates fail to meet Rule 12(b)(6)'s requirement that "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Relator's naked assertion that a single line item on one hospital's claims could increase composite payment rates for hospitals across the country is the textbook definition of speculative. So too is the very nature of the harm that Relator asserts to show materiality: that future reimbursement may, possibly, increase. *Iqbal*, 556 U.S. at 678 ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief'"); *see also Twombly*, 550 U.S. at 557.

Second, as the Supreme Court explained in its *Escobar* decision, the standard for establishing materiality is "rigorous" and "demanding," and requires that a relator plead the presence of materiality with Rule 9(b)-level particularity. 136 S. Ct. at 2004 n.6. So, even if the FAC passed muster under Rule 12(b)(6), it would still need to plead with particularity why and how the inclusion of allegedly inflated anesthesia time on Intermountain's claims will cause future DRG or APC rates to increase, which it does not.

Third, guidance issued by CMS, as well as numerous FCA decisions make clear that Relator's view is incorrect. CMS has taken the position that "as long as part of a bundled service is certain to be covered or medically necessary, *billing the entire bundled service as covered is*

appropriate." CMS, *Medicare Claims Processing Manual, Chapter 1—General Billing Requirements*, Pub. 100-04, § 60.4.3 (June 11, 2021) (emphasis added).[12] In preamble guidance, CMS also explained that:

> It should be noted in this regard that only if the *sole or primary* services (beyond routine care) provided to a patient are noncovered will the admission (and therefore prospective payment) be denied. This means that as long as an acceptable or proven diagnostic or treatment course (for the DRG) is present, even if noncovered care is also present, the payment will be made.

48 Fed. Reg. 39752, 39787 (Sept. 1, 1983). If, in fact, the allegedly inflated anesthesia services included on a hospital's claims seeking composite payments could improperly increase future rates, CMS would not take such a *laissez-faire* approach, nor would it expressly permit a hospital to include non-covered or non-reimbursable items on its claims.

Courts analyzing similar situations agree and have cast aside similar relators' arguments. In *United States ex rel. Kennedy v. Aventis Pharm., Inc*., the court noted that "a single hospital's cost report, or even several hospitals' reports, amount to a small portion of the data that inform the decision to increase or decrease DRGs." No. 03 C 2750, 2008 WL 5211021, at *5 (N.D. Ill. Dec. 10, 2008). The court in *Kennedy* further explained that "[s]everal other courts have recognized that individual charges on a patient bill are immaterial to the government's Medicare/Medicaid reimbursement decisions and, therefore, cannot serve as the basis of FCA liability." *Id*. at *3 (citing *United States ex rel. DiGiovanni v. St. Joseph's Candler Health Sys., Inc*., No. CV404-190, 2008 WL 395012, at *6 (S.D. Ala. Feb. 8, 2008); *United States ex rel. Magid v. Wilderman*, No. Civ. A. 96-CV-4346, 2004 WL 945153, at *9 (E.D. Pa. Apr. 29, 2004); *United States ex rel. Schell*

[12] Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf.

v. Battle Creek Health Systems, No. 1:00-CV-143, 2004 WL 784978, at *4 (W.D. Mich. Feb. 25, 2004), *rev'd on other grounds*, 419 F.3d 535 (6th Cir. 2005)).

Relator fails to state to claim for relief because he cannot plead—with particularity—that any alleged false statement on Intermountain's claims was material to CMS.

B. Relator fails to allege that Intermountain's claims were legally false

Relator makes two distinct but related arguments about Intermountain's alleged submission of legally false claims. First, Relator asserts that Intermountain made false certifications on its Technical Services claims when Intermountain represented that anesthesia services it provided were "reasonable and necessary," because the services provided by distracted MWA physicians fell below the standard of care. Second, Relator alleges that Intermountain made implicit certifications regarding its compliance with the Medicare conditions of payment or participation for hospitals, which were false given the MWA physicians' distraction. Both Relator's theories fail to state a claim for relief and require dismissal with prejudice under Rule 12(b)(6).

1. Relator's "reasonable and necessary" allegations fail to state a claim.

a) The "reasonable and necessary" standard governs whether an item or service is reimbursable, not how it is performed.

The centerpiece of Relator's legal falsity theory is his assertion that Intermountain provided "unsafe" or "substandard" anesthesia services which did not meet Medicare's "reasonable and necessary" requirement, rendering Intermountain's Technical Services claims ineligible for reimbursement, and its implicit certifications false. FAC ¶¶ 5–7. This argument is critically flawed. Leaving aside that the quality of care provided by MWA physicians—not Intermountain—is alleged to be substandard, and the faulty argument that MWA's services can somehow taint Intermountain's claims, Medicare's "reasonable and necessary" requirement

governs *whether* an item or service will be reimbursed, not *how* a particular item or service is rendered.

The Social Security Act provides that: "no payment may be made . . . for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). During the relevant timeframe for this action, no statute or regulation has defined the phrase "reasonable and necessary."[13] The sole guidance available to providers addressing the "reasonable and necessary" standard is found in the Medicare Program Integrity Manual. CMS, *Medicare Program Integrity Manual*, Pub. 100-08, § 13.5.1 (Feb. 12, 2019) ("PIM"). The PIM explains that an item or service is considered "reasonable and necessary" when it is: (1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients, including the duration and frequency considered appropriate for the item or service. *Id*. § 13.5.4.

The PIM standard speaks to whether an item or service is itself, safe and effective, experimental, or appropriate, and not if it was performed in a substandard way. FAC ¶¶ 5–6. Said differently, the "reasonable and necessary" standard is a coverage requirement that addresses whether items and services are reimbursable. *See* 86 Fed. Reg. 2987, 2988 (January 14, 2021) ("The Secretary has authority to determine *whether* a particular medical item or service is 'reasonable and necessary' under [the SSA]. When making coverage determinations, our policies have long considered whether the item or service is safe and effective, not experimental or

[13] CMS has issued a series of proposed rules which would clarify the definition of "reasonable and necessary" by codifying it within Medicare regulations. The proposed rules largely adopt the PIM's construction of "reasonable and necessary." 86 Fed. Reg. 2987 (January 14, 2021). The regulation is set to become effective on December 15, 2021. 86 Fed. Reg. 26849 (May 18, 2021).

investigational, and appropriate.") (emphasis added). Similarly, as the Court in *Mikes v. Straus* explained: "Section 1395y(a)(1)(A) mandates that *a provider's choice of procedures* be 'reasonable and necessary'; it does not obligate federal courts to step outside their primary area of competence and apply a qualitative standard measuring the efficacy of those procedures." 274 F.3d at 702 (emphasis added).

Despite this regulatory language, Relator offers a tortured interpretation of the "reasonable and necessary" standard by taking phrases like "[s]afe and effective" or "[f]urnished in accordance with accepted standard of medical practice" out of context to suggest they cover how an item or service is rendered. FAC ¶¶ 5–6. The authorities described above demonstrate why Relator is incorrect. So too, does *Polukoff*, a case Relator cites six times in his FAC. 895 F.3d 730; *see also* FAC ¶¶ 5, 34, 62, 107, 186, 206. In *Polukoff*, relator alleged that a physician performed unnecessary Patient Foramen Ovale ("PFO") closure procedures on patients whose clinical condition did not warrant them. 895 F.3d at 743. The Tenth Circuit held that relator sufficiently alleged the performance of PFO closures that were not "reasonable and necessary" because they did not adhere to industry and hospital guidelines a*bout whether and under what clinical circumstances PFO closure should occur*. *Id.* at 736–39. Nothing in *Polukoff* addressed whether the defendant physician performed PFO closure in an unsafe or substandard manner, because those considerations do not affect whether those procedures—or any others included on claims to Medicare—were "reasonable and necessary." In sum, Relator wrongly applies the "reasonable and necessary" standard to circumstances it does not address and fails to allege that Intermountain's claims contained false certifications.

b) Relator's "reasonable and necessary" theory is really a "worthless services" theory and should be evaluated under that standard.

Relator's "reasonable and necessary" claim is just a "worthless services" theory in disguise. In drafting the FAC, Relator carefully avoided asserting such a theory because he knows the standard for establishing a "worthless services" claim under the FCA is so impossibly high he has no hope of prevailing. However, as the Court reviews Relator's legal falsity arguments, that is precisely the standard it should apply.

Numerous federal circuits have adopted a "worthless services" theory of FCA that "allows a *qui tam* relator to bring claims for violations of the FCA premised on the theory that the defendant received reimbursement for products or services that were worthless." *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc*., 764 F.3d 699, 709–10 (7th Cir. 2014) (citing *Mikes*, 274 F.3d at 703). Under a "worthless services" theory, the performance of the service must be "so deficient that for all practical purposes it is the equivalent of no performance at all." *Chesbrough v. Visiting Physicians Ass'n, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (quoting *Mikes*, 274 F.3d at 702–03). Merely showing that the services a party provided were worth less than the amount it received in reimbursement cannot meet the bar for demonstrating "worthless services." *Absher*, 764 F.3d at 709. As the Court in *Absher* succinctly stated, "services that are 'worth less' are not 'worthless.'" *Id*. at 710.

For decades, the government and private relators have used the "worthless services" framework to pursue allegedly substandard or unsafe care rendered by healthcare providers. Any reasonable reading of the FAC evinces that purportedly "worthless services"—as opposed to medically unnecessary care—is precisely what Relator alleges. *See, e.g.*, FAC ¶ 3 ("To say this was substandard medical care is to understate the matter."); FAC ¶ 5 ("This substandard medical

practice turned into actionable fraud when Defendants billed the government for it."); FAC ¶ 187 ("[U]nsafe anesthesia services compromised the quality of the surgery as a whole . . . ").[14]

So, the Court should apply the correct standard when deciding Relator's "worthless services" allegation masquerading as a "reasonable and necessary" theory. When it does, dismissal for failure to state a claim under Rule 12(b)(6) is the only option. Rather than pleading that Intermountain failed to provide the surgical and anesthesia services on its claims, or that Intermountain's Technical Services were rendered so poorly they constituted no services at all, the FAC only alleges that Intermountain's care was substandard because of the MWA' physicians' lack of attention during surgery. FAC ¶¶ 15, 187. Under these circumstances, Relator has not met the high bar required to plead Intermountain's submission of claims for "worthless services," and his FAC should be dismissed.

c) Intermountain only certified that its own services—not those performed by MWA physicians—were "reasonable and necessary."

The FAC asserts that the MWA physicians' allegedly inattentive Professional Services render Intermountain's Technical Services not "reasonable and necessary," leading to false implied certification on Intermountain's claims for payment. As Relator vaguely alleges, the MWA physicians' use of their PEDs during surgery violated the "reasonable and necessary" requirement" leading to legally false claims "cover[ing] both the itemized [MWA] bills for anesthesia services *and the hospital bills for the inpatient stay* because the unsafe anesthesia service *compromised the quality of the surgery as a whole by elevating the risk to the patient from*

[14] Where a healthcare service offers "no medical value" it may also be actionable under a "worthless services" theory. *Chesbrough*, 655 F.3d at 468. The FAC makes no such claim about Intermountain's Technical Services.

the surgical procedure." FAC ¶ 187 (emphasis added). The Court should reject Relator's position for three reasons.

First, as explained in Section III.B.1.a, Relator fails to allege that MWA's Professional Services were not "reasonable and necessary" because Relator misapplies the Medicare requirement and incorrectly alleges that it reaches how services are performed when, in reality, it addresses whether a provider's choice of an item or service is reimbursable.

Second, as described above in Section III.A.1.b.ii., Intermountain's claims are distinct from those submitted by MWA because they: (1) seek payment for different items and services; (2) are governed by different billing rules and payment criteria; (3) are reimbursed by different components of the Medicare program; and (4) are submitted on different claim forms with different certifications. Even if Relator sufficiently alleged that MWA's services were not "reasonable and necessary"—which he has not—once the items and services provided by Intermountain are decoupled from those rendered by MWA, Relator's entire theory falls apart. Other than his deliberately ambiguous claim about the allegedly substandard service by MWA "compromising quality of the surgery as a whole," the FAC pleads no fact supporting Relator's view and offers no authority holding that Intermountain's claims rise and fall with MWA's. This is especially important, when even under Relator's invented "reasonable and necessary" standard, Intermountain is not alleged to have provided substandard or unsafe services itself.

Third, Intermountain's claims only made certifications concerning the items and services *it* provided, not the services provided by third-party physician group, MWA. Intermountain's certification on its CMS Form 1450 claims stated that: "submission of this claim constitutes certification that the billing information *as shown on the face hereof,* is true, accurate and complete." FAC ¶ 143 (emphasis added). Courts addressing this same issue—whether a hospital's

claims certifications cover the actions of independent physicians or groups—have reached the conclusion that they do not. *See United States ex rel. Thomas v. Bailey*, No. 4:06CV00465 JLH, 2008 WL 4853630, at *9–11 (E.D. Ark. Nov. 6, 2008) (concluding that a hospital's act of submitting a claim for payment, or a cost report, certifies that *the hospital* complied with certain laws but did not certify third party physicians' compliance); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (concluding relator alleged an FCA violation where *hospital* certified *its* compliance with health care laws knowing the certification to be false). Because hospitals do not have to make representations about third parties' compliance with statutory, regulatory, or contractual requirements, MWA's alleged performance of substandard or unsafe Professional Services cannot render Intermountain's certification on its own claims false.

2. Relator has not plausibly alleged a violation of either a condition of payment or a condition of participation that would lead to a legally false claim.

Relator asserts that Intermountain submitted legal false claims which contained misleading certifications because Intermountain purportedly violated Medicare conditions of payment or conditions of participation related to its provision of anesthesia services. FAC ¶¶ 192–96. But Relator's legal falsity theories fare no better than his allegations of factual falsity and should be dismissed under Rule 12(b)(6).

a) Relator's legal falsity theory based the conditions of payment is wholly derivate of his allegations concerning factual falsity and fail for the same reasons.

Relator asserts a wholly derivative theory of liability, that Intermountain's claims for Technical Services were legally false because they improperly certified compliance with Medicare's conditions of payment for anesthesia services. According to the FAC, MWA or Intermountain's failure to deduct time from their respective claims when the MWA physicians

were distracted with their PEDs violated the Medicare conditions of payment because they require "continuous care" to bill "anesthesia time." FAC ¶ 192; *see also* FAC ¶¶ 114–16.

Relator's legal falsity allegation is just a repackaged version of his factual falsity argument and fails for all the same reasons described in Section III.A., *supra*. To recap, Relator asserts a fictitious standard for billing anesthesia services that is untethered to what Medicare actually requires, any factual falsity on MWA's claims does not automatically render Intermountain's claims false, and even if Intermountain had improperly reported charges for anesthesia services on its claims—which it did not—it would not be material to Medicare reimbursement. Because Relator cannot show that Intermountain included factually false information on its claims, Relator also fails to plead a violation of any condition of payment, and a resulting false certification.

b) Relator has not sufficiently alleged a violation of the conditions of participation, nor would such a violation be material.

Relator's legal falsity allegations based on purported violations of the Medicare conditions of participation ("CoPs") also do not trigger a violation of the FCA. The FAC fails to allege an actual violation of the CoPs, and even if Relator had plead such a violation, it would still not be "material" to payment because the CoPs are enrollment standards, not conditions of payment.

To participate in the Medicare program, providers like Intermountain must submit an enrollment application to CMS, which includes a certification that the provider is in compliance with the thousands of potentially applicable statutes, regulations, and manual provisions. FAC ¶ 73. As the FAC notes, compliance with the CoPs is an enrollment standard to participate in

Medicare. *Id.* Many CoPs, including the five cited by Relator in the FAC speak to broad-based hospital operational issues and do not provide detailed standards about how care is administered.[15]

In fact, of the CoPs mentioned in the FAC, only one (42 C.F.R. § 482.52), can be reasonably interpreted as addressing the provision of anesthesia services at all. On that basis alone, Relator's allegations concerning the four other CoPs *that do not impose specific obligations on hospitals concerning anesthesia services* can be dismissed out of hand.[16] But even in the case of Section § 482.52, nothing in that regulation comes close to establishing standards concerning allegedly distracted anesthesiologists.

A close reading of Section 482.52 shows that while it requires the provision of anesthesia services in a "well organized manner" Relator makes absolutely *no* factual allegations, asserting that Intermountain did not provide anesthesia services or did so in a "disorganized" manner. Moreover, the requirements in Section 482.52 address what kind of practitioners can administer anesthesia, and what types of evaluations and anesthesia-related record keeping must occur. Nothing in Section 482.52 imposes obligations concerning the nature, frequency or intensity of anesthesia monitoring that must be provided, or more importantly, the hospital's purported role in

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[15] Relator cites CoPs at: 42 C.F.R. § 482.12 (Governing Body); § 482.13 (Patient's Rights); § 482.22 (Medical Staff); § 482.52 (Anesthesia Services); § 416.50 (Patient's Rights, ASC).

[16] Relator unbelievably argues Intermountain violated the CoP relating to informed consent by *not advising patients of their anesthesiologist's use of PEDs.* FAC ¶¶ 132–33, 137. This nonsensical abrogation of the actual language of the regulation does not yield a FCA violation. *See* CMS, *State Operations Manual Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*, Pub. 100-07, 439 (Feb. 21, 2020), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf ("[T]here is no specific requirement for informed consent within the regulation at § 482.52 *governing anesthesia services.* However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure."). In other words, hospitals may want to consider *general consent* to anesthesia—not the inclusion of any language regarding PEDs.

policing how anesthesiologists monitor patients. As a result, Relator does not adequately plead a violation of Section 482.52, or any other CoP.

Even if Relator could plead a violation of the CoPs, the violations alleged are not material to the government's payment decisions for purposes of an FCA claim.[17] As the Tenth Circuit noted in *Conner*, "[c]onditions of participation, as well as a provider's certification that it has complied with those conditions, are enforced through administrative mechanisms . . . conditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment." 543 F.3d at 1220.

Here, the administrative mechanism to address non-compliance with the CoPs outlined in 42 C.F.R. §§ 416.50, 482.13, the CMS State Operations Manual, and asserted in the FAC is the survey and enrollment process. *See* 42 C.F.R. § 488 (specifying plan of correction procedures for out-of-compliance providers). Under these regulations, CMS can take action against non-compliant providers, including through the imposition of fines and termination of enrollment. *Id.* Unless and until that occurs, however, the provider may submit claims and receive payment. Considering this, the CoPs cited are most certainly not material to the government's decision to pay. *Escobar*, 136 S. Ct. at 2003 ("A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.")

[17] This is particularly so where the actual Medicare payment amount would be the same regardless of the provision of anesthesia services. *See* discussion *supra* Section III.A.3.

Relator's argument that any violation of a condition of participation renders all claims fraudulent is misguided and fails as a matter of law. *See Conner*, 543 F.3d at 1220 (noting that considering [CoPs] material "would undermine the government's own administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into compliance when they fall short of what the Medicare regulations and statutes require."). On two occasions when the Tenth Circuit has weighed this precise issue (both before and after *Escobar*), the overwhelming conclusion reached was that monitoring healthcare providers' adherence with technical enrollment standards is the job of CMS, not courts at the behest of a *qui tam* relator. *See Janssen*, 949 F.3d at 545 ("not every regulatory foot-fault will enable Relators to avail themselves of the FCA's potentially costly damages awards"); *Conner*, 543 F.3d at 1221.

Finally, any alleged violation of a CoP (or a condition of payment, for that matter), is certainly not material given that the government has continued to pay such claims despite its knowledge of the instant lawsuit and Relator's allegations. Indeed, Relator filed this lawsuit in 2020. There can be no greater indication that the violations of CoPs alleged by Relator are not material to the government's decision to pay than the fact that the government has continued to pay such claims in full knowledge of Relator's allegations. *See Escobar*, 136 S. Ct. at 2003–04.

C. Relator's Claims Concerning Hospitals Other than Dixie Regional Medical Center do not Satisfy Rule 9(b)

Though Relator attempts to plead fraudulent activity that transpired all of Intermountain's hospitals, Relator's potential knowledge begins and ends with what he personally observed at the lone hospital where he practiced, Dixie Regional Medical Center ("DRMC"). FAC ¶ 217. As the FAC makes clear, Dr. Khoury practiced only at DRMC from 2007 through 2018. FAC ¶¶ 16, 23. On the basis of this experience, and his recollection of five allegedly distracted anesthesiologists

who practiced at DRMC (FAC ¶ 156–61), Relator alleges that Intermountain submitted false claims *throughout its entire system*. FAC ¶¶ 24–25, 28, 247. Relator does not even attempt, however, to allege facts sufficient to indicate the "who, what, where, when and how" of alleged fraudulent activity at other hospitals. FAC ¶¶ 151–84.

Neither does Relator allege that he attempted to obtain additional information to support his spurious claim. Relator does not allege that he spoke with surgeons or anesthesiologists *from other hospitals*. Though Relator alleges he spoke to the medical staff and leadership *at DRMC* about the issue of anesthesiologist use of PEDS, he tellingly makes no allegation that he learned anything about Intermountain practices, policies or procedures related to anesthesia *at any other location*. FAC ¶¶ 187, 191, 209–18.

Rule 9(b)'s purposes is to "afford the defendant[s] fair notice of plaintiff's claims and the factual ground upon which [they] are based." *Lemmon*, 614 F.3d at 1172 (quotations omitted). Relator has not satisfied that purpose concerning allegations relating to any Intermountain hospital other than DRMC. Pursuant to Rule 9(b), Relator's claims should be dismissed or otherwise limited to claims stemming from procedure performed at DRMC.

D. Relator Fails to Plead a Viable Conspiracy Claim

The FAC also offers an insufficiently pled claim that defendants conspired to violate the FCA under 31 U.S.C. § 3729(a)(1)(C). FAC ¶¶ 271–77. Relator's only allegations in support of this claim appear to be that defendants "coordinated" their efforts to inflate anesthesia time in medical records, permitted the use of electronic devices in the operating room, and "caus[ed] and condon[ed]" the making of false records. *Id.* "[G]eneral civil conspiracy principles apply to FCA conspiracy claims." *United ex. rel. Sorenson v. Wadsworth Brothers Constr. Comp.*, Case No. 2:16-cv-875, 2019 WL 2374386, at *5 (D. Utah June 5, 2019) (quoting *United States v. Toyobo*

Co., 811 F. Supp. 2d 37, 50 (D.D.C. 2011)). Relator must plead that defendants (1) conspired to submit a fraudulent claim; (2) that one or more of the conspirators performed an unlawful act in furtherance of that agreement; and (2) the United States suffered a resulting economic loss. *Sorenson*, 2019 WL 2374386, at *5.

As described in Sections III.A.–B., *supra*, Relator fails to establish that any defendant made a fraudulent claim under Section 3729(a)(1)(A) *or* made a false statement material to a claim under Section 3729(a)(1)(B). For this reason alone, Relator's conspiracy claim should be dismissed. *See Sorenson*, 2019 WL 2374386, at *5 (dismissing conspiracy claim where plaintiff had failed to establish fraudulent, material misrepresentations); *Salina Reg'l Health Ctr.*, 459 F. Supp. 2d at 1091 (dismissing conspiracy claim where there was no underlying FCA claim).

In addition, Relator has not set forth facts sufficient to allege that any of the defendants *made an agreement* to conspire together to submit a false claim to the United States, much less that any defendant committed an overt act in furtherance of such agreement. In Paragraphs 228–37 of the FAC Relator makes only conclusory statements that Intermountain and MWA "knew about this conduct" and "facilitated it to profit." FAC ¶ 229. This is not enough to state a claim for conspiracy. *See, e.g., United States ex rel. Poisson v. Red River Service Corp.*, 621 F. Supp. 2d 1153, 1156–57 (W.D. Okla. 2008). Neither are Relator's references to regulatory requirements for hospital functions or medical staff bylaws sufficient to state a claim for conspiracy. FAC ¶¶ 230–36. None of these routine (and in some case state-mandated) hospital functions amount to a "unlawful act" in furtherance of an "agreement" to violate the FCA. *See Sorenson*, 2019 WL 2374386, at *5.

E. Relator Fails to Plead a Viable Claim for Failure to Return Overpayments

Relator asserts that defendants knowingly "avoid[ed] an obligation to return money to the United States" when they failed to return payments for anesthesia services. FAC ¶¶ 238–45. But as Paragraph 281 of the FCA makes clear, Relator's "reverse-false-claims" cause of action is completely derivative of his causes of action alleging knowing submission of false claims or use of false records or statements material to a false claim. FAC ¶ 281.

Numerous courts have held that a plaintiff cannot establish a reverse false claim under 31 U.S.C. § 3729(a)(1)(G) based on the alleged retention of money received from the submission of a false claim. *See, e.g., United States ex rel. Lovato v. Kindred Healthcare, Inc.*, Case No. 15-cv-02759-CMA-NYW, 2020 WL 9160872, at *21 (D. Colo. Dec. 14, 2020) (dismissing reverse false claims predicated on submission of false claims or false statements in claims); *United States ex rel. Tra v. Fesen*, 403 F. Supp. 3d 949, 963 (D. Kan. 2019) (noting "numerous cases holding that section 3729(a)(1)(G) cannot be construed so as to be redundant with false claims and false records under subsections (a)(1)(A) and (a)(1)(B)"). Given that Relator predicates his reverse false claim count solely on conclusory allegations of false claims and false statements, Count Four for violation of 31 U.S.C. § 3729(a)(1)(G) should be dismissed with prejudice.

F. Relator's State Law Count Should Also be Dismissed

Relator also asserts a claim for violation of the Nevada False Claims Act ("NVFCA"). Nev. Rev. Stat. § 357.040. Relator posits that some of the persons who received surgery services at DRMC were beneficiaries of Nevada's Medicaid program—though he makes no specific allegations about such a connection. FAC ¶ 40. Regardless, Relator fails to state a claim as a matter of law under the NVFCA. The NVFCA is analogous to the federal FCA. Nev. Rev. Stat. § 357.040(1). For each of the reasons Relator fails to state a claim under the FCA,

Relator also fails to state a claim under the NVFCA. In the event the FCA claim is dismissed (as Intermountain urges it should be), this Court should decline to assert supplemental jurisdiction over any remaining NVFCA claims. 28 U.S.C. § 1367(c)(3).

G. The FAC Should be Dismissed with Prejudice and Without Leave to Amend

Relator's FAC fails to cure dispositive defects. This is despite Relator having multiple years and two attempts to plead this case successfully. Because of these repeated failures, the Court should dismiss Relator's FAC with prejudice. *Knight v. Mooring Cap. Fund, LLC*, 749 F.3d 1180, 1190 (10th Cir. 2014); *Gee*, 627 F.3d at 1195. Allowing Relator leave to amend would merely prolong the inevitable. His entire action is premised on legally flawed theories of liability that cannot be cured by pleading new, different, or more facts. *Brereton v. Bountiful City Corp.*, 434 F.3d 1213, 1219 (10th Cir. 2006). Accordingly, the Court should dismiss Relator's action, in its entirety, with prejudice.

IV. CONCLUSION

Based on the foregoing, Intermountain respectfully request that this Court dismiss with prejudice Relator's FAC, pursuant to Rules 9(b) and 12(b)(6).

Dated: August 31, 2021

Respectfully submitted,

/s/ Chad R. Derum

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CERTIFICATE OF SERVICE

On this 31st day of August 2021, I hereby certify that I electronically filed the foregoing **MOTION TO DISMISS FIRST AMENDED COMPLAINT AND MEMORANDUM IN SUPPORT** with the Clerk of the Court using the CM/ECF system that will send an electronic notification to counsel of record for all of the parties.

/s/ Chad R. Derum
Chad R. Derum